

### REMARKS

Claims 3, 17-23, and 25-29 were rejected, and claims 5-16, 24, and 31-46 were withdrawn from consideration. Thus, claims 3, 5-16, 17-29, and 31-46 remain pending. In addition, claims 28 and 29 have been amended to change "claims" to "claim." No new matter has been added by these amendments.

In light of the following, Applicant respectfully requests reconsideration and allowance of claims 3, 17-23, and 25-29.

#### Examiner Interview

Applicant's agent thanks Examiner Whiteman for the courtesy of the telephonic interview on February 4, 2005. The substance of this telephonic interview involved a discussion of the outstanding rejection under 35 U.S.C. § 112, first paragraph as well as the arguments presented herein.

#### Rejections under 35 U.S.C § 112, first paragraph

The Examiner rejected claims 3, 17-23, and 25-29 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. The Examiner appeared to base this rejection on the allegation that "one skilled in the art would determine that the only use for increasing BNP in a mammal is for use in a method of inhibiting or preventing heart failure in a mammal or to relax cardiac muscle in a mammal." (original emphasis).

Applicant respectfully disagrees. Independent claim 3 recites a method for increasing brain natriuretic peptide levels in a mammal. Contrary to the Examiner's allegation, Applicant's specification provides multiple uses for such a method. For example, page 46, lines 23-25 discloses increasing BNP levels to establish whether overexpression of BNP delays the progression of asymptomatic left ventricular dysfunction (ALVD) to overt congestive heart failure (CHF). Certainly, a person having ordinary skill in the art reading Applicant's specification would have been able to practice the presently claimed invention to achieve such a purpose without undue experimentation. This is particularly true given that Applicant's

specification discloses that injecting an adenoviral vector encoding BNP into the left ventricular myocardium not only increases coronary sinus BNP levels but also increases central venous BNP levels.

During the Examiner Interview on February 4, 2005, the Examiner questioned the ability of adenoviruses to increase BNP levels when administered systemically. Adenoviruses can be used to increase plasma BNP levels following systemic administration as evidenced by the Pan *et al.* reference (*Am. J. Physiol. Heart Circ. Physiol.*, 286:H2213-H2218 (2004)). For the Examiner's convenience, a copy of this reference is attached to the accompanying Information Disclosure Statement. As demonstrated in the Pan *et al.* reference, adenoviruses designed to express DNP, a snake natriuretic peptide with structural and functional similarities to mammalian natriuretic peptides, were injected into the tail vein of mice. Even though the authors stated that expression "after the tail vein adenoviral delivery in mice is primarily in the liver[,] an increase in plasma levels of DNP was demonstrated. *See*, right column on page H2216 and Figure 5 on page H2217. This evidence together with the teachings provided throughout Applicant's specification demonstrates that a person having ordinary skill in the art would have been able to make and use the presently claimed invention without undue experimentation. In fact, no undue experimentation is needed to make a nucleic acid molecule encoding BNP and administer that nucleic acid molecule to a mammal to increase BNP levels. Thus, Applicant's specification fully enables present claims 3, 17-23, and 25-29.

In light of the above, Applicant respectfully requests the withdrawal of the rejection of claims 3, 17-23, and 25-29 under 35 U.S.C. § 112, first paragraph.

Applicant : Robert Simari  
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### CONCLUSION

Applicant submits that claims 3, 17-23, and 25-29 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned attorney at the telephone number below if such will advance prosecution of this application. The Commissioner is authorized to charge any fees or credit any overpayments to Deposit Account No. 06-1050.

Respectfully submitted,

Date: February 7, 2005

  
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J. Patrick Finn III, Ph.D.  
Reg. No. 44,109

Fish & Richardson P.C., P.A.  
60 South Sixth Street, Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696